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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/072,177

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Robert E. Fischell

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EXAMINER

WANG, SHENGJUN

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

03/13/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/072,177	<b>Applicant(s)</b> FISCHELL ET AL.	
	<b>Examiner</b> Shengjun Wang	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 5-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 23-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Receipt of applicants' remarks, and the declaration under 37 C.F.R. 1.132 submitted December 7, 2007 is acknowledged.

#### ***Claim Rejections 35 U.S.C. 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-4 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iyer et al. (US 6,726,923), in further view of Berg et al. (USPN 6,068,654).

3. Iyer describes a drug-eluting biodegradable matrix comprising rapamycin for treating anastomosis. (see col. 18-22). The matrix of Iyer is capable of being wrapped around tissues of a human body, because it is perivascularly wrapped around site of interest. The matrix of Iyer is biodegradable and stable (see col. 4, lines 10-col 5, line 40). Iyer encourages the use of other anti-inflammatory such as dexamethasone with rapamycin. (col. 6, lines 55-67). The matrix is particularly useful for wrapping T-shaped vascular vessel joint, wherein the matrix cover the joint as a sleeve. See, particularly, figures 6-13 and column 13, lines 14-20. As it is obvious, a centrally-located hole for placement onto a vessel is taught. See, figures 1-3, and columns 12, lines 7-58.

4. Iyer et al. do not teach expressly a matrix with annular shape and radial edge.

However, as revealed by Berg et al., T-shaped Joint location of vascular vessel is normally in the shape of a circle, and the connector of the joint is in the shape of annular. See, the figures.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make the matrix of Iyer into an annular wrap with radial edge, as the annular shape would have been a obvious variation of the square shape disclosed by Iyer, particularly in view of the fact that the T-shaped vascular vessel joint is normally in the shape of a circle. As to claims 23 and 24, reciting slit or cut extending toward the edge, it is noted the optimization of the physical shape of the wrap so to accommodate the shape of the vascular vessel being wrapped is a matter of engineering optimization and would have been within the purview of ordinary skill in the art.

5. Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iyer et al. (US 6,726,923), in view of Berg et al. (USPN 6,068,654), and in further view of Casey (USPN 3,902,497).

6. teachings of Iyer et al. and Berg et al. have been discussed above. Iyer et al. and Berg et al. do not teach expressly the biodegradable material be oxidized regenerated cellulose.

7. However, Casey teaches that oxidized regenerated cellulose is a well-known biodegradable material absorbable in tissues. See, column 2, lines 38-42.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make the matrix of Iyer et al. by using the oxidized regenerated cellulose as the biodegradable material because oxidized regenerated cellulose is a

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well-known biodegradable, bioabsorbable material, and the employment of oxidized regenerated cellulose is seen to be a selection from amongst equally suitable material and as such obvious.

Ex parte Winters 11 USPQ 2<sup>nd</sup> 1387 (at 1388).

***Response to the Arguments***

Applicants' remarks, and the declaration under 37 C.F.R. 1.132 by Dr. Andrew Penman have been fully considered, but are not persuasive for reasons discussed below.

8. The declaration under 37 CFR 1.132 filed December 7, 2007 is insufficient to overcome the rejection of claims 1-4, 23-28 based upon Iyer et al. (US 6,726,923), Berg et al. (USPN 6,068,654), and Casey (USPN 3,902,497), as set forth in the last Office action because:

9. The declaration asserts that the cited references in the rejections are directed to different technologies and therefore are not "compatible". The declaration essentially argue that the two secondary references, Berg et al. and Casey et al. are non-analog art. The arguments are not persuasive. It has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the cited references are reasonably pertinent to the particular problem with which the applicant was concerned. Particularly, Berg is cited to show the particular shape of claimed article would have been obvious. Casey is cited to show that oxidized regenerated cellulose is a well-known biodegradable material absorbable in tissues.

10. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

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11. Applicants contend that a prima facie case of obviousness of the claimed invention over Iyer et al and Berg et al., as Berg et al. do not teach drug delivery device. The arguments are not persuasive, for reasons as discussed above related to non-analogue arguments.

1. Applicants' attention is further directed to KSR vs. Teleflex, where the court states: "When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. **If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.**" The only difference between Iyer et al. and the claimed invention, is the shape of the sheet which are used for wrapping tissue, particularly, vascular vessel. Optimizing the shape of a sheet so to properly fit with the wrapped tissue would have been within the purview of a ordinary skilled artisan. Berg is cited to show the claimed shape would have been obvious.

As to the argument of Casey reference, it is noted that Iyer et al. teach the employment of biodegradable material. Casey teach the particularly material employed herein is a known biodegradable material absorbable in tissues. Applicants are reminded that the question under 35 U.S.C. 103 is not merely what reference expressly teach, but what they would have suggested to one of ordinary skill in the art at the time the invention was made; all disclosures of prior art, including unpreferred embodiments, must considered. In re Lamberti and Konort (CCPA), 192 USPQ 278.

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shengjun Wang/  
Primary Examiner, Art Unit 1617

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